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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/087,871	06/02/98	WAGNER G	0708-4038

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MORGAN & FINNEGAN
345 PARK AVENUE
NEW YORK NY 10154

EXAMINER	
GABEL,G	
ART UNIT	**PAPER NUMBER**
1641	6

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/087,871	Wagner
Examiner	**Group Art Unit**
Gallene R. Gabel	1641

☒ Responsive to communication(s) filed on *Sep 27, 1999*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-21* is/are pending in the applicat

Of the above, claim(s) *13-21* is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-12* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-21* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *2*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

Election/Restriction

1. Applicant's election of Group 1, claims 1-8, with traverse, is acknowledged and has been entered. Applicant's traversal is on the grounds that the restriction requirement set forth is improper for the following reasons: 1) Applicant notes that the restriction requirement in the previous Office Action sets forth that Invention II is directed to a process and Invention IV is directed to an apparatus and that the Examiner reasoning is inapposite, thereby rendering the requirement improper, 2) the inventions are obvious over each other within the meaning of 35 USC 103, 3) it would not be duly burdensome for the Examiner to search all fields of inventions.

Examiner thanks the applicant for pointing out the oversight as noted in 1) and sets forth, herewith, a line of reasoning as applicable to statutory subject matter.

In light of applicant's argument, the restriction requirement as previously set forth is withdrawn and restriction requirement of the following inventions are currently required under 35 U.S.C. 121:

I. Claims 1-12, drawn to a diagnostic system comprising different analyzers for performing biological marker measurements, classified in class 422, for example.

II. Claims 13-15, drawn to computer program and computer readable medium, classified in class 266, subclass 80, for example.

III. Claims 16-21, drawn to method of using automated diagnostic system and apparatus, classified in 128, subclass 632, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions (diagnostic system and computer program) have different modes of operations, different functions, and different effects wherein the diagnostic system performs analysis of various biochemical markers using various reagents and the computer program is coded so as to allow communication between central and local processors.

Inventions I and III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, Invention I can be performed using basic manually programmed analyzers.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions (computer program and process of using the diagnostic system) have different modes of operation, different functions, and different effects wherein the computer program is coded so as to allow communication between central and local processors and the

process comprises analyzing various biochemical markers by measuring concentration levels, thereof.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classifications and recognized divergent subject matter, restriction for examination purposes as indicated is proper. Moreover, because the search required for Group I is not required for Group II, and the search required for Group II is not required for Group III, restriction for examination purposes as indicated is proper.

Inventions I, II, and III are not obvious over each other on the grounds that Invention I is drawn to a diagnostic system comprising analyzers, Invention II is drawn to a computer program, and Invention III is drawn to a method for performing biological measurements using the diagnostic system.

Lastly, Examiner has met her burden of demonstrating that each of the Inventions is patentably distinct from the others by determining that each group is searched under separate classifications and by providing explanation for separate classifications and by providing separate utility for each apparatus, process, and computer program. See MPEP § 806.05(d). In showing that these inventions are distinct by acquiring a separate status in the art as shown by their different classifications, Examiner deems restriction for examination purposes indicated as proper. Furthermore, literature search for each apparatus, process of use, and computer program is distinct since the structural requirements of each invention are different. While exhaustive searches would be expected to overlap, there is no reason to expect the searches to be

coextensive. Applicant's contention that examination of all the claims would not pose undue burden to the examiner is, therefore, without merit for reasons aforementioned.

The restriction requirement as currently set forth is deemed proper and is therefore made FINAL.

Applicant has provisionally elected Group I, claims 1-8, with traverse. Examiner rejoined claims 9-12 into Group I, in light of applicant's argument. Claims 13-21 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Currently, claims 1-12 are pending and under examination.

Drawings

2. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite in reciting "to execute measurements specified by a program executed by the processor in order to facilitate diagnosis of a pathology" because it does not clearly define what specific elements encompasses the metes and bounds of the "measurements". See also claims 2, 5, 7, and 8.

X Claim 6 is vague and indefinite in reciting "wherein said processor supports the diagnosis of the pathology" because it is unclear what is encompassed by the term "supports".

Claim 7 is indefinite and unclear in reciting "wherein the diagnosis of the pathology for the subject is based, at least in part, on results from the measurements executed according to said reflex algorithm" because it does not specifically define what is encompassed by the recitation of "at least in part", i.e. abnormal results or elevated results, etc.

Regarding claim 7, the phrase "additional stored information" renders the claim indefinite because the claim includes elements not actually disclosed (those encompassed by "additional"), thereby rendering the scope of the claim unascertainable. See MPEP § 2173.05(d).

Claim 8 is indefinite in reciting "wherein said measurements specified by the program include a measurement executed by the hematology analyzer in response to a command from said processor" because it does not clearly define what specific elements encompasses the metes and bounds of the "measurements", i.e. do these measurements further comprise the "elements" recited in claim 1.

Claims 1 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting

to a gap between the necessary structural connections. See MPEP § 2172.01. Claim 8 fails to specify what element in the hematology analyzer communicates with the processor so as to enable it to respond and execute specific commands.

Regarding claim 9, the term "including" renders the claim indefinite because it is unclear what other the limitations following the term are included in the claimed invention. See MPEP § 2173.05(d). See also claim 10.

The preamble in claim 9 is indefinite, inconsistent, and confusing as to the interactive relationships between elements within the claim. Please clarify. See also claim 10.

Claim 10 lacks antecedent support for reciting "said individual".

Claim 10, line 17 is non-idiomatic and , therefore, confusing in reciting "**concerning** outputs". See also claim 11, line 3.

Claim 10, line 20 has improper antecedent basis problem in reciting "a biological marker measurement". Change to --the biological marker measurement-- for proper antecedent basis.

Claim 11 fails to recite a positive statement in reciting "selectively **suggests** an indication of a pathology according to the reflex algorithm" because it does not specifically define what encompasses the term "suggests". For example, does the term "suggest" imply a diagnosis of a pathology or disease?

Claim 12 is vague, confusing, and recites inconsistent language by reciting "each includes a respective processor in communication with said processor because it fails to differentially identify or specifically define between "main" processors and "local" processors.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

As set forth in *In re Wands,* 858 F .2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988), the factors to be considered in determining whether a claimed invention is enabled throughout its scope without undue experimentation include the quantity of the experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of prior art, the relative skill of those in the art, and the breadth of the claims.

4. Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for acute myocardial infarction biochemical markers, does not reasonably provide enablement for other biochemical markers, such as thyroid profile markers and hepatitis profile markers. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

As to the biochemical markers, the direction and guidance in the specification is notably limited to specific acute myocardial infarction markers, such as total creatine kinase, myoglobin, troponin I, etc. The working examples, likewise are limited to the cardiac markers. Based on this limited disclosure and direction, one of the skill in the art would not know how to use alternative

biochemical markers, such as thyroid profile markers in the instant diagnostic system which comprise immunoassay analyzer, clinical chemistry analyzer, and hematology analyzer, without undue experimentation.

5. Claim 9 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for automated immunoassay analyzers and clinical chemistry analyzers, does not reasonably provide enablement for other assay means for performing measurements, such as individual assay kit means and manually programmed assay means. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claim.

As to the assay means for performing biochemical marker measurements, the direction and guidance in the specification is notably limited to automated analyzers and processors, etc. The working examples, likewise are limited to the automated biochemical assays. Based on this limited disclosure and direction, one of the skill in the art would not know how to use alternative means of measuring such as assay kits, means of processing information such as visual interpretation of a reaction, and means of storing information such as record keeping, in the instant diagnostic system, without undue experimentation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lillig et al. (US 4,965,049) in view of Groth et al. (US 5,690,103) and in further view of Furlong et al. (Clinical Chemistry, 1990).

Lillig et al. disclose a system of modular analyzers each adapted for independent operation and each possessing different operational characteristics for different applications (see Abstract). The system includes at least a first analyzer, i.e. immunoassay and a second analyzer, i.e. clinical chemistry, each including a sample carousel, analyzing means, and automated probe means for transferring samples from the sampling carousels to the analyzing means. When analyzers are combined to form a broad-capability system, the analyzers utilize a single sample handling device (loading system) (see column 2, lines 8-23). Each modular analyzer is adapted to operate as a portion of a system of modular analyzers (see column 3, lines 55-58). Analysis means comprise analysis modules which include a sample receiving port and is adapted to receive sample volumes from the probe and perform analyses thereon (column 3, lines 1-4). Electronic and electrical interfaces (public or private networks) are provided between the analyzers to form a system. Computer processors (interface cards) provides a program, data, and timing signals via cabling. Program and data signals include operational information and instructions entered into the modular analyzer through the disk drive (see column 6, lines 51-65). Operating software for one or more local (micro)processors in the modular analyzer may be

loaded from the disk drive to suitable memory means within each modular analyzer (see column 7, lines 4-8).

Lillig et al. differs in failing to teach diagnostic nature of the modular analyzer system. Lillig et al. are silent in the teaching of analyte assays and thereby, fail to disclose analysis of biochemical markers.

Groth et al. disclose detection or exclusion of acute myocardial infarction (AMI) using reflex algorithm (computer based neural network analysis) in biochemical marker measurements. Groth et al. specifically disclose diagnostic categorization of AMI based on frequent timed blood sampling and measurement of selected biochemical markers with different rates of appearance in circulating blood (see Abstract). Reflex algorithm or neural network is a computational structure which is trained on a representative set of preclassified example cases, prior to application in unknown cases. Biochemical markers of AMI include myoglobin, creatine kinase, and cardiac troponins T and I and are selected such that they have different rates of appearance in plasma (see column 5, lines 22-26). Diagnosis is generated by comparing measured concentrations or enzymatic activities with positive and negative standards and/or results from previous AMI/ non-AMI patients. Each step comprises a measure of biochemical markers wherein results either indicative or nonindicative of AMI based upon comparison procedures are generated, following the neural network methodology (see column 5, lines 45 to column 6, line 29 and Figure 1). Groth et al. disclose that this diagnostic system is implemented in a computer system (central processor) designed in a modular fashion, where each module performs a specific task of

computation (see column 8, lines 6-34). Figure 4 is a data flow diagram where computational processes and data flows are indicated. Measurements of infarct markers can be performed with the use of decentralized analyzers with short turn around times.

Furlong et al. teach a diagnostic system based on reflex algorithm (computerized neural network analysis) of serial cardiac enzyme data for use as clinical decision-making aid (see Abstract). Neural networks are hardware and software emulations of biological nervous systems, formed by many interconnected artificial neurons (see page 135, column 1, first full paragraph). Furlong et al. studies criteria for diagnosing acute myocardial infarct using biochemical markers (cardiac enzymes) as listed in Table 1 and column 1 and applies it in neural network design. Furlong et al. also further teach that some artificial intelligence programs make use of algorithmic process for decision a making wherein clinicians knowledge is distilled in a hierarchy of facts or rules (see page 134, column 2, last paragraph). Furlong et al. teach that neurons from one layer generally are synapsed to neurons of subsequent layer wherein synapses are assigned random excitatory or inhibitory algebraic weighting factors (page 135, column 2, second full paragraph. The matrix of synaptic weighting factors are calculated using back propagation, supervised learning algorithm.

It would have been obvious to one ordinary skill in the art at the time of the invention to incorporate computer-based neural network analysis as taught by Groth et al. and Furlong et al. into the modular analyzer system as taught by Lillig et al. because Groth et al. specifically disclose application of his teaching into decentralized analyzers in order to expedite analysis of

patient samples in emergency situations and Furlong et al. specifically teaches that the neural network has proven to be a useful adjunct to traditional methods. One of ordinary skill in the art at the time of the invention would have been motivated to increase automated diagnostic versatility into the high-throughput capacity of modular designed analyzer systems by incorporating therein, decision support systems such as the computerized neural network as taught by Groth et al. and Furlong et al. because in assessing proper emergency management of crisis patients, especially those suspected of myocardial infarction, specific and accurate results obtained at a limited amount of time coupled with anticipatory diagnostic procedure, are critical to the treatment and survival of patients.

Remarks

11. Prior art made of record are not relied upon but considered pertinent to the applicants' disclosure:

Jackowski et al. disclose a device for diagnosing and distinguishing chest pain and early onset, thereof.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gail Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday to Thursday from 7:00 AM to 4:30 PM. The examiner can also be reached on alternate Fridays from 7:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

10/31/99

Gailene R. Gabel
Patent Examiner
Art Unit 1641

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641